Products, Partnerships & Public Health --- Technology Licensing From NIH

Stephen Finley

Technology Licensing Specialist, Division of Technology Development & Transfer

NIH Office of Technology Transfer

Email: sf31w@nih.gov



NIH Licensing: Transfer of Commercial Rights From Biomedical Research Program

- Annual budget of \$ 23.3 billion (2002)
- 10% of funding for intramural research
- 4,500 doctoral scientists /19,000 staff
- 35,000 grantee investigators
- Basic & clinical research discoveries
- Partners commercialize into products

Future Commercial Products Licensable From Several Sources

- Intramural Research (from the NIH Office of Technology Transfer)
- University Grantee Research (from specific university technology transfer offices)
- SBIR and STTR Programs (from small business awardees)

Characteristics of the NIH Intramural Research Program "Pipeline"

- Novel, fundamental research discoveries
- "Supermarket" for research tools
- CRADA partnerships for basic or clinical studies
- Selected products in early clinical trials
- Product sales by licensees exceed \$ 3B

NIH Research Collaborations



NIH Research Collaborations

- Cooperative Research And Development Agreement (CRADA) - for-profit
- Clinical Trial Agreement
- Specialized Development Services
- Training Programs

NIH Product Licensing Principles

- Granting only the appropriate scope of rights
- Permit research uses
- Preference for non or partial exclusivity
- Specified fields of use
- Enforceable benchmarks

NIH License Types

- Exclusive Patent
 Commercialization
- Non-exclusive Patent Commercialization
- Non-exclusive Patent Internal Use
- Commercial Evaluation License

- Biological Material Commercialization
- Biological Material Internal Use
- Interference or Dispute
 Settlement
- Inter-institutional

Types Of Royalties In NIH Licenses

- Execution Royalty
- Minimum Annual Royalty (regardless of the amount of Net Sales
- Earned Royalties (fixed % of Net Sales)
- Benchmark Royalties
- Patent Costs

Typical Factors Influencing NIH Royalty Rate Negotiations

- Stage of Development
- Type of Product
- Market Value of Product
- Uniqueness of Materials

- Scope of Patent Coverage
- Market Timing
- NIH "Content"
- Public Health

Typical Commercial Evaluation License

- Non-exclusive
- Materials provided / screening not permitted
- Feasibility testing only
- Short term (<18 mo.) paid-up license
- Modest cost
- Products: immortalized liver cells

Typical Research Products License (Internal Use)

- Non-exclusive
- Materials provided / screening use permitted
- No reach through to products
- Larger firms predominant
- Paid-up term licenses or annual fees
- Products: muscarinic receptor

Typical Research Products License (Commercialization)

- Non-exclusive
- Materials provided (patented or unpatented)
- Smaller firms predominate as licensees
- High earned royalty rates
- Low upfront costs
- Products: CHAPS, antisera, mabs

Diagnostic & Therapeutic Products Licensed From NIH



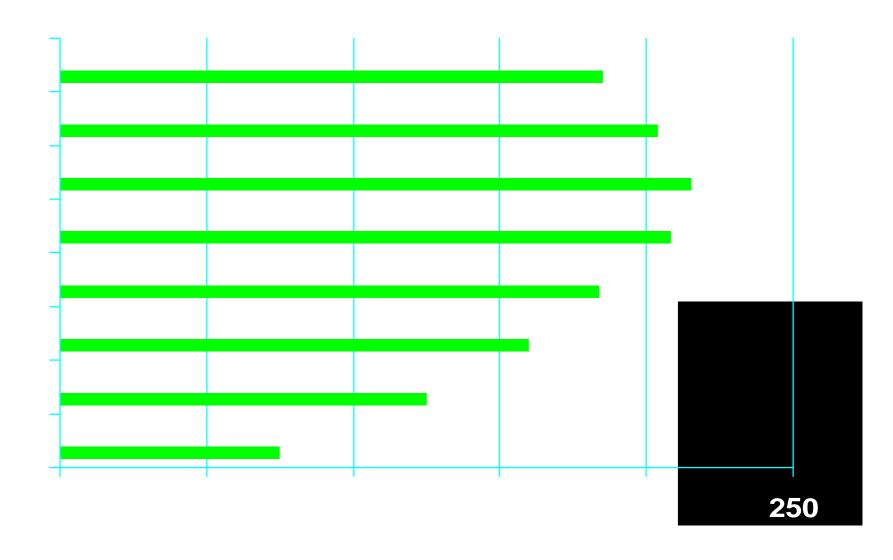
Typical Vaccine, Diagnostic Or Therapeutic License

- Exclusive if required for development
- Most major pharma or biotech have at least one
- Detailed development plan with benchmarks
- Preference for capable small firms
- CRADA research separate from license
- U.S. manufacturing for U.S. product sales

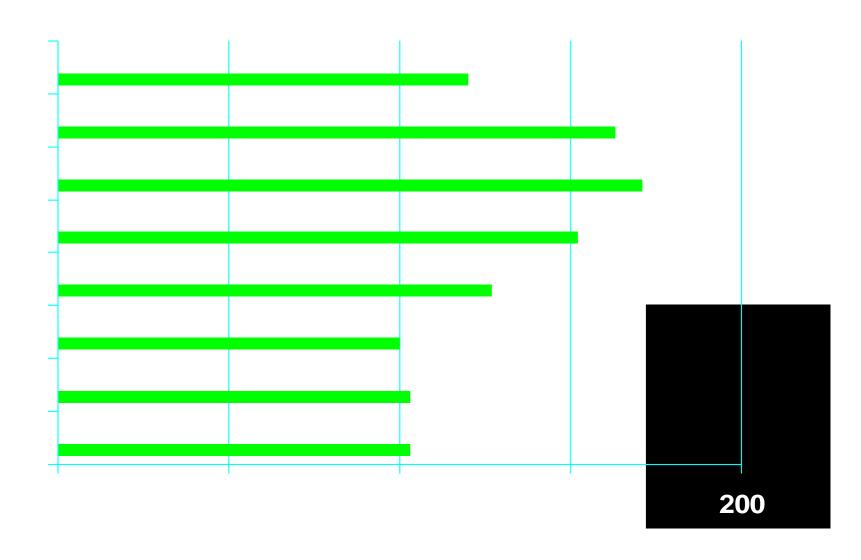
Typical Vaccine, Diagnostic Or Therapeutic License (Cont.)

- Substantial upfront fees
- Moderate earned royalties
- Appropriate benchmark payments
- Share sublicensing payments
- "White Knight" provisions
- Monitor performance of licensee

NIH Executed Licenses

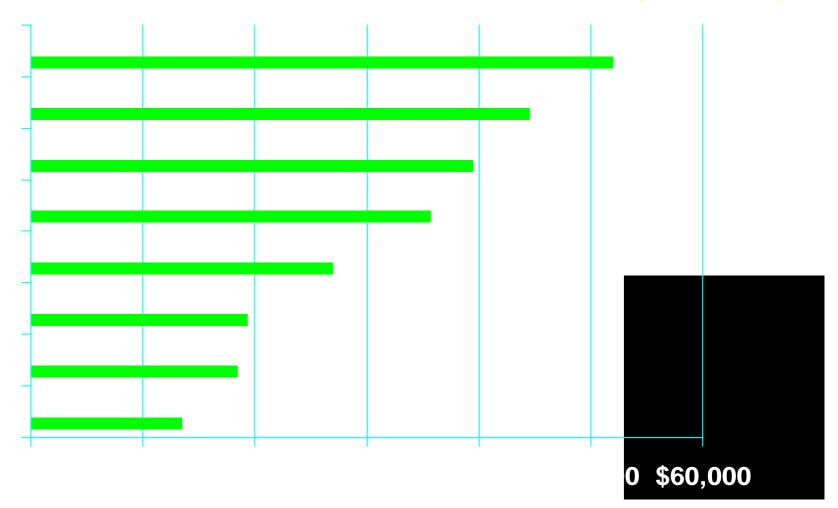


NIH Issued Patents



NIH Royalties

(\$\$ in 000s)



NIH "Homerun" Licensed Products

• Abbott HIVAB (AIDS Test Kit)

• BMS Videx (ddI)

• BMS Taxol (paclitaxel)

• Schering Fludara (fludarabine)

• SKB Havrix (hepatitis A)

• Roche Hivid (ddC)

Recent NIH Products Approved

• Diatide AcuTect (DVT imaging)

• Genzyme Thyrogen (rTSH)

• Isis Vitravene (antisense CMV)

• Medimmune Synagis (RSV mab)

• NAV Certiva (DPT vaccine)

• Wyeth RotaShield (rotavirus)

Sources Of Information On NIH Licensing And Technologies

- NIH Technology Transfer ott.od.nih.gov
- CRISP Database nih.gov/grants
- Pharmalicensing pharmalicensing.com
- Technology Exchange tech-ex.com
- University Ventures uventures.com
- Pharma-transfer pharma-transfer.com
- Knowledge Express keonline.com